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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/068,812

02/04/2002

Richard J. Greff

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EXAMINER

GHALI, ISIS A D

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

01/20/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/068,812	GREFF, RICHARD J.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Isis A. Ghali	1611	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 November 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-38 and 42, 43, 45-47 is/are pending in the application.
- 4a) Of the above claim(s) 34-38, 43 and 45-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-33 and 42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The receipt is acknowledged of applicant's amendment and request for RCE, both filed 11/10/2009.

Claims 22-38, 42, 43, 45-47 are pending.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/10/2009 has been entered.

#### ***Response to Election/Restrictions***

2. Claims 43, 45-47 filed 01/13/2009 are directed to an invention that is independent or distinct from the invention originally claimed and prosecuted. In the final office action dated 06/10/2009, the examiner inadvertently added the following paragraph that may caused some confusion, and applicants were not required to elect between inventions I and II. The inadvertently added paragraph as follows:

"The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention."

Therefore, applicants were not required to elect between inventions I and II because shift of the invention is not permitted at this stage of prosecution. According to MPEP 819 [R-3], the office generally does not permit shift. The general policy of the Office is not to permit the applicant to shift to claiming another invention after an election is once made and action given on the elected subject matter. Note that the applicant cannot, as a matter of right, file a request for continued examination (RCE) to obtain continued examination on the basis of claims that are independent and distinct from the claims previously claimed and examined (i.e., applicant cannot switch inventions by way of an RCE as a matter of right). When claims are presented which the examiner holds are drawn to an invention other than the one elected, he or she should treat the claims as outlined in MPEP § 821.03.

The invention of claims 43, 45-47 is distinct from the originally prosecuted invention of claim 22 for the following reasons: claims 43, 45-47 are directed to composition comprising crosslinked gelatin, wetting agent and saline solution; and further comprises syringe assembly comprises a holding chamber, an injection port, a luer hub ejection port, and a cannula. Instant claim 22 does not require saline solution or the syringe assembly having specific structure as claimed by claims 45-47. Invention

of claims 22-33 and 42 and invention of claims 43, and 45-47 are unrelated because the different inventions have different design, and consequently different mode of operation and different effect. The invention of claims 22-33, and 42 does not require specific syringe assembly or saline for application, rather can be applied directly to the wound.

According to MPEP 821.03 [R-3], the claims for different invention added after an office action should be treated as indicated by 37 CFR 1.145 that concerns "subsequent presentation of claims for different invention". This section of MPEP states "If, after an office action on an application, the applicant presents claims directed to an invention distinct from and independent of the invention previously claimed, the applicant will be required to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review as provided in § 1.143 and 1.144".

Applicants state that examiner previously examined kit claims with a syringe, however, the kit claim was only one claim comprising the hemostatic composition and a syringe, and did not require any specific structure of the syringe as instantly claimed invention of claims 43, 45-47. The syringe of the kit was treated as a package as it did not require structural/functional limitation.

3. Since applicant has received an action on the merits for the originally presented invention of claims 22-33, and 42, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, **claims 43, 45-47 are withdrawn** from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

**Claims 22-33 and 42 are included in the prosecution.**

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 22-25, 27-30, 32, 33, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Pawelchak et al. (US 4,292,972, IDS filed 03/06/2003).

Current claim 22 is directed to a composition comprising: a cross-linked gelatin sponge and a wetting agent that is soluble in a non-aqueous solvent.

Pawelchak disclosed sponge product comprising hemostatic bioabsorbable cross-linked gelatin foam (abstract; col.3, lines 18-22, 30-33, 44-46; the claims). The product comprises from about 10% surface tension modifier including polyoxyethylene derivatives of sorbitan fatty acid esters, such as Tween 60 (col.4, lines 47-56). The surface active agents disclosed by the reference are identical to those instantly claimed as wetting agents, and inherently are soluble in non-aqueous solvents. Pawelchak further disclosed up to 30% glycerin (col.5, lines 35-40; examples 6 and 18), which also reads on wetting agent and inherently are soluble in non-aqueous solvents. The reference disclosed method of making the foam by forming dispersion containing aerated foamed gelatin and adding the surfactant and/or glycerin to the dispersion,

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followed by drying of the dispersion and forming a sponge product (col.4, lines 40-47, 60-68; col.5, lines 1-2). Adding the surfactant and/or glycerin to the dispersion containing foamed aerated gelatin meet the limitation of coating the gelatin with the wetting agent as instantly claimed by claim 28 because applicants coated the gelatin foam by soaking the foam in dispersion containing the wetting agent. The product is sterilized and packaged (col.5, lines 3-8). Although reduction of the hydration time is directed to the intended use of the product, however, the product disclosed by the reference that comprises cross-linked gelatin and the same wetting agent inherently decreases the hydration time of the cross-linked gelatin that claimed in claim 22. The foamed sponge further comprises antimicrobial agent and hemostatic agent such as thrombin (col.5, lines 29-35). The solubility and absorbability of the foam product can be reduced by reducing cross-linking (col.3, lines 36-39).

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pawelchak et al. in view of JP 02-182259 ('259).

The teachings of Pawelchak are discussed above.

Although Pawelchak teaches anionic surfactants, however, does not explicitly teach alkyl (C<sub>6</sub>-C<sub>20</sub>) sulfate salts, aryl (C<sub>6</sub>-C<sub>10</sub>) sulfate salts, and alkaryl (C<sub>7</sub>C<sub>24</sub>) sulfate salts as claimed by claim 26.

JP '259 teaches composition comprising cross linked gelatin impregnated with surfactant (abstract). The surfactants include sodium lauric sulfuric acid, polyethylene glycol alkyl ether and sorbitan fatty acid ester (page 7, second full paragraph).

Therefore, at the time of the invention, it would have been obvious to one having ordinary skill in the art to provide hemostatic composition comprising cross linked gelatin sponge and anionic surfactant (wetting agent) as taught by Pawelchak, and replace the anionic surfactant with sodium lauric sulfuric acid taught by JP '259. One would have been motivated to do so because JP '259 teaches the equivalency between sodium lauric sulfuric acid, polyethylene glycol alkyl ether and sorbitan fatty acid ester as anionic surfactant added to the hemostatic gelatin sponge product. One would reasonably expected formulating hemostatic composition comprising cross linked gelatin foam and sodium lauric sulfuric acid that has hemostatic effect.

10. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pawelchak in view of EP 5568 334 ('334).

The teachings of Pawelchak are discussed above.

Although Pawelchak teaches hemostatic agents incorporated into the gelatin foam product, however the reference does not specifically teach growth factor as claimed by claim 31.

EP '334 teaches sponge comprising cross linked gelatin and active agent, preferably growth factors which enhances wound healing and nerve regeneration (abstract; col.5, lines 22-30).

Therefore, at the time of the invention, it would have been obvious to one having ordinary skill in the art to provide hemostatic product comprising cross linked gelatin sponge, anionic surfactant and hemostatic agents as taught by Pawelchak, and add the

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growth factor taught EP '334 to the sponge. One would have been motivated to do so because EP '334 teaches that growth factors are preferred active ingredient to be added to hemostatic wound treating composition comprising gelatin because growth factors enhance wound healing and nerve regeneration. One would reasonably expected formulating composition comprising cross linked gelatin foam, anionic surfactant and growth factors wherein the composition successfully and effectively enhances wound healing and nerve regeneration.

### ***Response to Arguments***

11. Applicant's arguments with respect to claims 22-33, 42 have been considered but are moot in view of the new ground(s) of rejection.

### ***Contact Information***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

IG

/Isis A Ghali/  
Primary Examiner, Art Unit 1611